Transitioning to a computer-based intervention for women with gestational diabetes mellitus

Jessica Murray

Faculty Advisor: Diane Berry, PhD, ANP-BC, FAANP

UNC Chapel Hill School of Nursing

Honors Candidate

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Abstract

Health promotion remains important for all individuals, especially for those at risk for developing chronic disease. Many women are diagnosed with gestational diabetes mellitus while in their second trimester of pregnancy, and this puts them at risk for developing type 2 diabetes mellitus later in on in life. *Optimizing Outcomes in Women with Gestational Diabetes and their Infants* is a randomized controlled two group repeated measures design that offers a nutrition and exercise education and coping skills training intervention to help women to improve eating and exercise behaviors and lose weight postpartum. The ultimate goal for this study is to reduce the risk of women diagnosed with gestational diabetes mellitus from developing type 2 diabetes mellitus later in life. Although enrollment was successful, it was difficult and took slightly longer than projected. In addition, many women returned to work 6 weeks postpartum due to financial necessity. Therefore, a new way to deliver the intervention was needed for future studies. A review was conducted examining other forms of intervention delivery and a decision was made by the research team to make the following changes. An online interactive educational program was designed to guide future participants through information on general health, nutrition and exercise education and coping skills training, and an at-home tabletop easel was created with the same information for home use. The tabletop easel was designed to allow mothers to teach their families about the importance of exercise and nutrition. These two changes will be tested in future studies.

Introduction

When planning a research study with human participants, it is important to evaluate the most effective way to implement the intervention of choice. Traditional health promotion interventions have included face-to-face educational sessions; however, recently there has been a move to transitioning education to the internet (Knowlden & Sharma, 2014). Online education programs have been found to be convenient and efficient. The research study through the UNC Chapel Hill School of Nursing, *Optimizing Outcomes in Women with Gestational Diabetes and their Infants*, has an extensive nutrition and exercise education and coping skills training intervention that is taught in small group classes over a 14-week period (Berry, et al., 2013). Previous studies were analyzed to compare traditional group interventions and online interventions to find a more efficient way to deliver the intervention in future studies.

Literature Review

Research studies that implement interventions at a specific location require the commitment of participants and the research team to find common days and times that work for all. Webster and colleagues (2011) conducted a study that examined what women were exposed to throughout their pregnancy including chemicals, dust, and pollutants while at home, work and during recreational activities. The study required participants to attend intervention classes, laboratory blood draws, home visits, and a research assistant at the time of delivery to obtain a cord blood sample (Webster). Webster and colleagues (2011) found it difficult to enroll pregnant women in their first trimester secondary to many women not finding out they were pregnant until the end of their first trimester and the stress sometimes associated with the diagnosis of pregnancy. Webster's study (2011) provided insight on designing studies that are acceptable to newly diagnosed pregnant women.

Shere, Zhao and Koren (2014) found that 60% of randomized controlled studies failed to recruit adequate participants and had to extend their recruitment deadline. Therefore, they conducted a study with pregnant women comparing two modes of recruitment including enrollment in the clinical setting and enrollment through social media (Shere, et. al.). Pregnant women have been a difficult group to enroll in research studies secondary to many competing interests such as work, medical appointments, and preparing for the arrival of their new infant (Shere, et al.). Shere and colleagues (2014) found that putting recruitment materials, advertisements and additional healthcare information on social media websites, that their enrollment increased 12-fold. This study was able to demonstrate a unique way to increase enrollment that was acceptable to participants and streamlined the process.

Knowlden and Sharma (2014) found that it was difficult for parents to commit to traditional classroom activities. The research team developed an online program that included content on parenting and a process evaluation component (Knowlden & Sharma). Knowlden and Sharma (2014) found that not only did the intervention need to be taught differently, but adjustments needed to be made in how telephone data collection, online surveys, and email notifications were made. This made all aspects of the study online which would not require in-class participation. They also found that incorporating all of these new methods increased efficiency and lowered attrition rates (Knowlden & Sharma).

As technology has evolved, research has advanced its methods as well. There are many digital and electronic programs that deliver educational programs. Distribution of information through the internet is convenient. However, many low-income participants may not have computers and may not be able to afford internet connections to download certain programs

(Knowlden & Sharma, 2014). Web-based interventions also need to include effective process evaluation for continual program improvement (Knowlden & Sharma).

Online based interventions have been used in situations where there is a need for convenience and when participants felt particularly vulnerable. A qualitative study was done to see if there was a benefit from having online support groups for patients with gynecological cancer in comparison to the usual in-person support groups hosted by the clinics and hospitals (Wiljer, et al., 2011). The study had a way to track how often each participant logged in, how often they posted comments, and their feedback about the program and discussion topics (Wiljer). This study had developed processes to clearly track use, acceptance, and feedback to improve intervention delivery and provide information to build future programs. Patients with gynecological cancer may have private questions they may want to ask; however, they may feel uncomfortable discussing those questions in person (Wiljer). This online support group opened up the opportunity for these women to ask questions that they may have hesitated asking in person (Wiljer). Generally, they felt the program was convenient and improved support as they went through treatment (Wiljer).

Another study focused on mental health and online support groups (Barak and Grohol, 2011). Online programs related to mental health include support groups, e-therapy, psychoeducational websites, and self-guided psychotherapy interventions (Barak and Grohol). Psychoeducational websites promote the idea of providing information to participants; however, these websites are clear that the website cannot take the place of regular meetings with a therapist (Barak and Grohol). Many psychoeducational websites provide general health education, symptom identification, and self-help strategies, but there is no personalization of care (Barak and Grohol). According to Barak and Grohol (2011), a more interactive and personalized

approach would be self-guided psychotherapy interventions. Each intervention is designed to be specific to a general type of person or psychiatric issue, and topics are added or deleted based on the person's progress and/or responses (Barak and Grohol). The interactive aspect has worked more effectively in anxious patients compared to depressed patients, so depending on the type of person, a different educational tool may work better (Barak and Grohol). Online interventions have been tested in a variety of ways and have provided convenient interactive education, which is important for both recruitment and retention in research studies.

Study

Optimizing Outcomes in Women with Gestational Diabetes and their Infants is a research study that is testing the feasibility and initial efficacy of a 14-week intensive nutrition and exercise education and coping skills training intervention designed for women diagnosed with gestational diabetes mellitus (Berry, et al., 2013). The requirements for all participants include two laboratory appointments for blood samples, five data collection appointments, and 14 group intervention meetings (Berry, et al., 2013). The research team coordinates laboratory appointments, data collections, and intervention classes on the same days to streamline the process. The minor obstacles that arose during the recruitment and intervention phase of this study included difficulties scheduling appointments for women, varying commitment levels of participants, and the unpredictability of having expectant and new mothers as participants (Personal Communication, Dr. Diane Berry, August 15, 2013). Discussions with the research team and participants found that the requirement for participants to attend class weekly may be one of the reasons why commitment and attendance has not been as high as initially expected.

During the summer 2013, I completed a research practicum on the study and was able to work with Dr. Berry, the lead principal investigator, Ms. Madeline Neal, project manager, and

Ms. Emily Gail Hall, field coordinator. During this time, I was able to work with the research team to analyze areas for improvement. For my honors project, I chose to focus on transitioning how the intervention was implemented because the research team felt that was one important way to improve recruitment and retention.

Population

Pregnant women face many barriers when joining a research study, including a lack of time, lack of resources, and a lack of reliable transportation (Personal communication, Dr. Diane Berry, August 15, 2013). In *Optimizing Outcomes in Women with Gestational Diabetes and their Infants* the research team started to recruit women soon after they were diagnosed with gestational diabetes mellitus (Berry, et al., 2013). According to the American Diabetes Association [ADA] the time period of diagnosis for gestational diabetes is normally around the 24th week (6th month) of pregnancy (ADA, 2014). Enrolling women during their 6th month of pregnancy eliminates the barrier of first-trimester women who are just finding out that they are pregnant. Women during their 6th month of pregnancy who are diagnosed with gestational diabetes mellitus have numerous doctor appointments. Therefore, committing to another obligation, such as a research study, may be overwhelming. Knowlden and Sharma (2014) found that the time commitment required of participants to participate in person remains a significant barrier to intervention studies. Tierney and colleagues (2010) studied pregnant women's eating and weight status and found that many times it was difficult to recruit women because they were not willing to admit they were having issues with eating or weight. Tierney and colleagues (2010) examined women who had a history of eating disorders including anorexia, bulimia, over indulgence, or transitions between extreme dieting. Results demonstrated that women were

willing to admit that they needed to change their lifestyles choices regarding eating and their weight once they participated in the health promotion intervention (Tierney, et al.).

Recruitment for *Optimizing Outcomes in Women with Gestational Diabetes and their Infants* identifies the study population as women with gestational diabetes mellitus (Berry, 2011). In women with gestational diabetes, it is imperative to lose weight postpartum, improve nutritional intake and increase exercise to prevent the development of type 2 diabetes mellitus later in life (ADA, 2014). It may be difficult for women to not only come to terms with the diagnosis of gestational diabetes mellitus, but to also understand the long term ramifications for both themselves and their children (Berry, et al., 2014). Therefore, it is important to tailor interventions and meet women where they are in their lives. Increasing the convenience and the method of receiving the nutrition and exercise education and coping skills training classes designed for women with gestational diabetes mellitus may improve both interest and completion of the program. Working with the research team, the 14 weekly classes were refashioned to be delivered in the convenience of the home setting through two modalities which will be tested in a future comparative effectiveness study according to Dr. Berry.

Intervention Delivery Modification

For the first intervention modification, I worked with the research team to modify the 14 classes into online modules. This will provide a more convenient method for mother's to self pace their nutrition and exercise education and coping skills training classes. Once the mother has mastered the classes, as measured by pre and post tests,

they will be coached to then teach their family the content of the intervention. There have been few studies that have compared in person to online studies. One study analyzed the mental health of post-disaster victims via a web-based intervention (Price, Gros, McCauley, Gros, & Ruggiero,

2012). The researchers found that the web-based intervention was hard to track and that only 44% of the participant completed the study (Price, et al.). The researchers were unsure why the completion rate was so low. They felt access to the internet and familiarity with navigating the internet may have added to their low rates of completion (Price, et al.). Therefore, when implementing the revised computer-based intervention, phone coaching will be implemented to assure participants are comfortable navigating the website. In addition, pre and post tests will be electronically captured through the internet into the database, which will allow further tracking and troubleshooting the on-line program and evaluating how the content is being received by the participants.

The second intervention modification includes an educational tabletop easel that includes the information for all 14 classes. The educational easel was created for the mother to be able to teach her family the information that she learned through the online educational program. Once the mother has mastered the classes as measured by pre and post tests she will then be coached to teach her family the content by using the easel. Each woman will administer a pretest to her age appropriate family members, teach her family members the module, and then conduct a post-test to evaluate their knowledge gained. The mother will then discuss her finding with the study participants.

Conclusion

Through revising the methods on how the nutrition and exercise education and coping skills training classes are delivered to new mothers in the comfort of their own home, both recruitment and retention may improve. The overall goal is to empower women to not only improve their health, but to also become the agent of health change in her family and support their families through improved nutrition, exercise and problem solving.

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